National Mutual Acceptance
of ethical and scientific review for multi-centre clinical trials
conducted in public health organisations

FACT SHEET

Aims

(a) Enable Public Health Organisations of participating jurisdictions to accept a single ethical and scientific review of multi-centre Clinical Trials; and
(b) Inform the ongoing development of the national system of single ethical and scientific review of multi-centre research.

Under the national mutual acceptance agreement a multi-centre clinical trial will be reviewed for ethical and scientific merit once only. There will be exceptions in the case of First Time in Human (FTIH), Phase 0 and Phase 1 trials in Australian Capital Territory, Northern Territory and South Australia which will require review within that jurisdiction. Other exemptions apply in each jurisdiction.

Scope of clinical trial research

Interventional research involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that have been conducted. This may include observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.
This includes commercially sponsored, Collaborative Groups and Investigator Initiated clinical trial research.

Reviewing Human Research Ethics Committees (HREC)

The single ethical and scientific review of a multi-centre Clinical Trial is to be conducted by an appropriate NHMRC Certified HREC in a participating jurisdiction.

Selecting a reviewing HREC

For applicants to select a reviewing HREC the following will apply:
- In Queensland, through the Central Co-ordinating Service (website booking form: http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp)
- In Victoria, through a Central Allocation System (Phone: 03 9096 7395)
- In Australian Capital Territory, New South Wales and the Northern Territory the choice of HREC is at the discretion of the applicant.
- In South Australia and Western Australia applications should be to the Certified HREC associated with the site at which the applicant is conducting the research and if this is not applicable, the selection of the Certified HREC is at the discretion of the applicant.
- through the Tasmanian HREC once certified; prior to that at the discretion of the applicant

The HRECs, RGOs and Organisations guidance document contains contact details and can be found on jurisdictional websites.

Ethics Application forms

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The National Ethics Application Form (NEAF) is required to be used for application to a Certified HREC.

For studies in the Australian Capital Territory the Australian Capital Territory Specific Module must be completed in addition to the NEAF.

For studies in Victoria the Victorian Specific Module must be completed in addition to the NEAF.

For studies in Western Australia the Western Australian-Specific Module must be completed in addition to the NEAF.

HREC Monitoring and Reporting

The reviewing HREC will have oversight of the clinical trial and ensure that it complies with all ethical, scientific and safety requirements, as appropriate. Investigators will be required to provide regular progress reports, other required reports and safety reports to the reviewing HREC (according to the NHMRC Position Statement (http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf).

The Monitoring and Reporting Tables outline the requirements for each participating jurisdiction including local site reporting requirements and can be found on jurisdictional websites.

Site Specific Assessment (SSA)

The National Mutual Acceptance scheme provides for ethical and scientific approval only. Each participating Public Health Organisation must undertake site specific assessment (SSA) of a multi-centre clinical trial and be authorised in compliance with the relevant jurisdictional standard operating procedures.

Each jurisdiction will have a SSA form for use within that jurisdiction.

Types of clinical trial research exempt from single ethical and scientific review

For research conducted in the Australian Capital Territory

- Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the single ethical review system for institutions under the ACT public health system. Where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will undergo ethical and scientific review by ACT Health HREC. Applications will be subject to standard research governance (site specific assessment) requirements.
- All human research projects requiring access (including linkage) to territory data collections owned or managed by the ACT Government must be reviewed by the ACT Health HREC
- All human research projects involving persons in custody in the ACT and/or staff of ACT Justice Health require review by the ACT Health HREC
- Research studies involving access to coronial material must be reviewed by the ACT Health HREC

- Approval from the ACT Health HREC is required where the research project involves research in, or concerning:
    - The experience of Aboriginal and Torres Strait Islander people as an explicit focus of all or part of the research;
    - Data collection explicitly directed at Aboriginal and Torres Strait Islander people;
    - Aboriginal and Torres Strait Islander people, as a group, are to be examined in the results;
    - The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or
    - Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in New South Wales

All human research projects involving persons in custody in NSW and/or staff of NSW Justice Health require review by the NSW Justice Health HREC.

Approval from the Aboriginal Health and Medical Research Council Ethics Committee is required where the research project involves research in, or concerning, NSW and any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research;
- Data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

All human research projects requiring access (including linkage) to statewide data collections owned or managed by NSW Health or the Cancer Institute (NSW) must be reviewed by the NSW Population and Health Services Research HREC.

For research conducted in the Northern Territory:

- Phase 0 (first time in human) and Phase 1 clinical trials will **n**ot be accepted under the single ethical review for clinical trials for Northern Territory public health system institutions. Where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will be re-reviewed ethically by the appropriate HREC in the Northern Territory in addition to any research governance (site specific assessment) requirements.
- Approval from the appropriate NT HREC is required where the research project involves research in, or concerning:
    - The experience of Aboriginal and Torres Strait Islander people as an explicit focus of all or part of the research;
    - Data collection explicitly directed at Aboriginal and Torres Strait Islander people;
    - Aboriginal and Torres Strait Islander people, as a group, are to be examined in the results;
    - A significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin;
    - The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or

- Aboriginal and Torres Strait Islander health funds are a source of funding.

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For research conducted in Queensland

Research studies involving access to coronial material must be referred to the Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals.

For research conducted in South Australia

Phase 0 and Phase 1 clinical trials will be exempt from single ethical review in South Australia.

Approval from the Aboriginal Health Research Ethics Committee (AHREC), South Australia, will be required where:

- The experience of South Australian Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- Data collection is explicitly directed at South Australian Aboriginal and Torres Strait Islander people; or
- Where it is proposed to separately identify South Australian Aboriginal and Torres Strait Islander people in the results; or
- The information has an impact on one or more South Australian Aboriginal and Torres Strait Islander communities; or
- The geographic location of the research is such that a significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the *National Statement,* 2007); or
- Where terms such as 'resilience'; 'well-being'; 'cultural safely'; 'cultural health'; and 'language and culture' are used in the description and design of the project indicating that the project has important health implications for South Australian Aboriginal and Torres Strait Islander people; or
- South Australian Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in Tasmania

- Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the single ethical review system for institutions under the Tasmanian public health system. Where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will undergo ethical and scientific review by Tasmanian HREC. Applications will be subject to standard research governance (site specific assessment) requirements.
- All human research projects requiring access (including linkage) to Tasmanian data collections owned or managed by the State Government must be reviewed by the Tasmanian HREC
- All human research projects involving persons in custody in Tasmania and/or staff of the Department of Justice require review by the Tasmanian HREC.
- Research studies involving access to coronial material must be reviewed by the Tasmanian HREC
- Approval from the Tasmanian HREC is required where the research project involves research in, or concerning:

- The experience of Aboriginal and Torres Strait Islander people as an explicit focus of all or part of the research;
- Data collection explicitly directed at Aboriginal and Torres Strait Islander people;
- Aboriginal and Torres Strait Islander people, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or
- Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in Victoria
Research studies involving access to coronial material must be referred to the Victorian Institute for Forensic Medicine HREC.

Research studies involving persons in custody require review by the Justice HREC of Victoria.

For research conducted in Western Australia
All clinical trials, where Aboriginality is a key determinant or is explicitly directed at Aboriginal people, must be reviewed by the Western Australian Aboriginal Health Ethics Committee.

All clinical trials that require access to coronial samples, data or information must be reviewed by the Coronial Ethics Committee, WA.

All clinical trials that require the use and disclosure of personal information from the Department of Health data collections or data linkage must be reviewed by the Department of Health WA HREC.

Jurisdiction contacts and websites

Australian Capital Territory
Research Office
Phone: 02 6174 7968
Email: acthealth-hrec@act.gov.au
Web: http://healthresearch.anu.edu.au/human-research-ethics-committee.html

New South Wales
The Office for Health and Medical Research
Phone: 02 9391 9920
Email: healthethics@doh.health.nsw.gov.au
Website http://www.health.nsw.gov.au/ethics/Pages/default.aspx

Northern Territory
Office of the Chief Health Officer
Phone: 08 8999 2768
Email: barbara.paterson@nt.gov.au

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Queensland
Health and Medical Research
Phone 1300 753 227
Email hmr@health.qld.gov.au
Website http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

South Australia
Office for Research Development
Phone: 08 8226 6367 or 08 8463 6145
Email: researchethics@health.sa.gov.au
Website: www.sahealth.sa.gov.au/researchethics

Tasmania
Office of the Chief Medical Officer
Phone: 03 6233 8530
Email: john.milbourne@dhhs.tas.gov.au

Victoria
Coordinating office for Clinical Trial Research
Phone: 03 9096 7394
Email: multisite.ethics@health.vic.gov.au
Website: www.health.vic.gov.au/clinicaltrials/

Western Australia
Research Development Unit, Office of the Chief Medical Officer
Department of Health WA
Phone: 08 9222 4332
Email: CMOResearchDevelopment@health.wa.gov.au
Website: www.health.wa.gov.au/researchdevelopment/home/multi_centre.cfm